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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,789	06/23/2006	Philippe Teissier	033339/313045	1481

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1781	

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04/25/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,789	TEISSIER, PHILIPPE	
	Examiner	Art Unit	
	HAMID R. BADR	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-12,16-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-12,16-19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 2/17/2011 is acknowledged.

Rejection of claims 1, 3-5, 7-10, 12, 16-19 and 21-22 under 35 U.S.C. 112 second paragraph is withdrawn per applicants' amendment .

Claims 1, 3-5, 7-12, 16-19 and 21-22 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 11 recites the limitation "before granulation" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-5, 7-12, 16-19 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santus (US 5,952,021; hereinafter R1) in view of Rutherford et al. (US 5,292,657; hereinafter R2) (Both references are of record)

6. R1 discloses a method of preparing and coating of microgranules comprising microorganisms. The microgranules can be suspended in foodstuffs such as milk and milk products and fruits juices. (Abstract)

7. R1 discloses that the microgranules have a size range of 50-400 micron before coating. The microgranules are coated with at least one coating to acquire a particle size of 50-500 microns. The coated microgranules may be added to food products such as milk, milk products, fruit and vegetable juices (col. 3, lines 45-67). It is noted that the pH and the water content limitations of claim 1 are both intrinsic in fruit and vegetable juices as well as fermented milk products such as buttermilk. R1 discloses citrus juice as an example of the food products to which these microgranules may be added. (col. 8, line13)

8. R1 discloses a preferable range for the particle size of 90-300 microns for the inventive microgranules. (col. 4, lines 63-64)

9. The coating of microgranules may comprise a single enteric layer. The coatings may comprise more layers of hydrophobic or hydrophilic materials that may be applied to the microgranules before or after the enteric coating. (col. 5, lines 14-20)

10. R1 teaches of incorporating probiotic organisms such as Bifidobacteria, Lactobacilli, Streptococci; etc. into the microgranules. (col. 5, lines 27-36)

11. R1 discloses the preparation of microgranules comprising lyophilized Lactobacillus acidophilus and Bifidobacterium longum cells. The granules being free of starch. (Examples 2, 3 and 4)

12. While R1 discloses that the microgranules may have a hydrophobic coating, R1 is generally silent regarding coating materials such as food waxes, fatty acids, fats and oils as presently claimed.

13. R2 discloses a process for preparing microspheres of freeze-dried microorganisms coated with fatty material. (Abstract)

14. R2 discloses a fatty matrix such as stearic acid having a melting point of 40—75C. R2 also teaches that mixtures of fatty acids may by used. As long as the fatty acid is solid at room temperature it meets the requirement(Col. 2 line 62- Col. 3, line7). R2 further discloses that their method produces even coating on the microorganisms and the even coating together with the hydrophobic nature of the saturated fatty acids would produce coated microorganisms, particularly bacteria, which are stable even when subjected to some moisture and antibiotics. The stability being predicted for 3 to 6 months. (col. 3, lines 55-64). Given that hydrophobic materials such as saturated fatty acids are disclosed by R2, saturated fatty acids and other hydrophobic materials falling within the melting point range as disclosed by R2 would obviously be candidates for coating microorganisms.

15. R2 discloses that bacteria such as Lactobacilli, and Bacillus can be used in the process (Col. 3, lines 13-16).

16. R2 discloses that the particles (granules) contain 50%-over 90% by weight of the fatty component. (Col. 3, lines 21-23).

17. R2 discloses the particle size range of 75-300 microns with the preferred range being less than 250 microns. (Col. 4, lines 7-9).

18. Given that R2 discloses the use of freeze-dried (lyophilized) bacteria, the use of a lyoprotectant, as commonly practiced in the lyophilization of bacteria, is inherent in the process of freeze-drying disclosed by R2. The particle size of the bacteria and the water activity of the freeze-dried culture are also inherent in the freeze-dried bacterial culture. Dehydrated lactic acid bacteria are well known to be adversely affected by high water activity in their media and a water activity of less than 0.4 is a well established level, for dehydrated lactic bacteria, commonly practiced in the art.

19. Given that a freeze-dried culture is used in the process by R2, the number of dormant organisms in the dehydrated culture will depend on the initial number of those organisms in the culture broth before freeze-drying. It is noted that the total number of the dehydrated organisms in freeze-dried (lyophilized) samples are usually in the range10^8-10^12 CFU/g, therefore, the bacterial count per gram of the product as presently claimed is obvious in view of the bacterial counts commonly encountered in lyophilized cultures. .

20. Despite the fact that applicants have provided/claimed a specific strain of Lactobacillus casei (i.e. I-1518) to be incorporated into microgranules, this does not provide a patentable distinction over those strains disclosed by R1 or R2 as also being incorporated as probiotics into microgranules, absent any clear and convincing

evidence and/or arguments to the contrary. Alternatively, given the specific teachings of R2; one would have been motivated to routinely prepare microgranules comprising the claimed strain being coated with hydrophobic materials as disclosed by R2.

21. In summary, R1 clearly discloses the incorporation of microgranules of probiotic organisms into liquid foods such as fruit juices. R1 also disclose that such microgranules may be coated using hydrophobic coating materials. R2 teaches of preparing microgranules using hydrophobic materials.

22. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to prepare microgranules of probiotic organisms including the claimed strain, for incorporation into liquid foods as taught by R1 using the hydrophobic materials for coating as disclosed by R2. One would do so to protect the lyophilized Lactobacilli from environmental factors such as moisture, oxygen, acidity; etc. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in producing liquid foods such as fruit juices containing live probiotics.

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

In light of the new ground(s) of rejection, applicants' arguments are moot.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 1781

Hamid R Badr
Examiner
Art Unit 1781